Complete Summary

GUIDELINE TITLE

1) Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. 2) December 2009 addendum.

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for breast cancer. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2009 Dec.

U.S. Preventive Services Task Force. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2009 Nov 17;151(10):716-26, W-236. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Screening for breast cancer: recommendations and rationale. Ann Intern Med 2002 Sep 3;137(5 Part 1):344-6. [10 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
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SCOPE

DISEASE/CONDITION(S)

Breast cancer

GUIDELINE CATEGORY

Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Obstetrics and Gynecology
Oncology
Preventive Medicine
Radiology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations and supporting scientific evidence on screening for breast cancer
- To update the 2002 USPSTF recommendations on screening for breast cancer

TARGET POPULATION

Women 40 years or older who are not at increased risk for breast cancer by virtue of a known underlying genetic mutation or a history of chest radiation

INTERVENTIONS AND PRACTICES CONSIDERED

1. Film mammography
2. Digital mammography
3. Magnetic resonance imaging (MRI)
4. Clinical breast examination (CBE)
5. Breast self-examination (BSE)

MAJOR OUTCOMES CONSIDERED

Key Question 1a: Does screening with mammography (film and digital) or magnetic resonance imaging (MRI) decrease breast cancer mortality among women ages 40 to 49 years and 70 years and older?

Key Question 1b: Does clinical breast exam (CBE) screening decrease breast cancer mortality? Alone or withÂ mammography?

Key Question 1c: Does breast self-examination (BSE) practice decrease breast cancer mortality?

Key Question 2a: What are the harms associated with screening with mammography (film and digital) and MRI?

Key Question 2b: What are the harms associated with CBE?

Key Question 2c: What are the harms associated with BSE?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review update was prepared by the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Search Strategies

EPC staff searched the Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews (through the fourth quarter of 2008) and the MEDLINE database (January 1, 2001 to December 1, 2008) for relevant studies and meta-analyses (Appendix B1 in the Evidence Synthesis [see the "Availability of Companion Documents" field]). EPC staff also conducted secondary referencing by manually reviewing reference lists of key articles and searching citations by using Web of Science, particularly searching for follow-up data from screening trials cited in the previous evidence review. Appendix B2 in the EvidenceÂ Synthesis (see the "Availability of Companion Documents" field) shows the search results.

Study Selection

Studies were selected on the basis of inclusion and exclusion criteria developed for each key question. Studies identified from theÂ searches that did not meet inclusion criteria are listed in Appendix B3 in the Evidence Synthesis (see the "Availability of Companion Documents" field). To determine the effectiveness of screening, EPC staff included randomized controlled trials and updates to previously published trials of screening with mammography (film and digital), magnetic resonance imaging (MRI), clinical breast examination (CBE), or breast self-examination (BSE) with breast cancer mortality outcomes published since 2001. One trial was translated into English from Russian for this update. EPC staff also reviewed meta-analyses that included studies with mortality data. EPC

staffÂ excluded studies other than controlled trials and systematic reviews or those without breast cancer mortality as an outcome.

Harms of screening were determined by using evidence from several study designs and data sources. For mammography, searches were focused on recently published systematic reviews and meta-analyses of radiation exposure, pain during procedures, patient anxiety and other psychological responses, consequences of false-positive and false-negative tests, and overdiagnosis. EPC staff also conducted specific searches for primary studies published more recently than the included systematic reviews and meta-analyses. In addition, EPC staff evaluated data from the Breast Cancer Surveillance Consortium (BCSC), which is a collaborative network of 5 mammography registries and 2 affiliated sites with linkages to pathology and/or tumor registries across the United States, that is sponsored by theÂ National Cancer Institute. These data draw from community samples that are representative of the larger, national population and may be more applicable to current practice in the United States than other published sources. Data include a mix of film and digital mammography. For harms of CBE and BSE, EPC staffÂ reviewed screening trials of these procedures that reported potential adverse effects, utilized recently published systematic reviews, and conducted focused searches.

EPC staffÂ included studies of the cost effectiveness of screening that were relevant to the key questions and target population (Appendix C1 in theÂ EvidenceÂ SynthesisÂ [see the "Availability of Companion Documents" field]). EPC staffÂ excluded studies evaluating the cost of improvingÂ screening rates (e.g., post-card reminder versus telephone reminder), dual review of screeningÂ mammography, screening education programs, or studies of patients with a history of breast cancer or who were at high risk for developing breast cancer. EPC staffÂ highlighted studies that expressed outcomes in quality-adjusted life-years (QALY). The QALY incorporates changes in length and quality of life, expressed as the extra dollars (cost per QALY ratio) required to achieve 1 extra QALY. A year in perfect health is considered equal to 1.0 QALY.

NUMBER OF SOURCE DOCUMENTS

See Appendix B2 in the Evidence Synthesis (see the "Availability of Companion Documents" field) for information about the number of studies identified for each Key Question.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Decision Analysis
Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review update was prepared by the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF). Additionally, six modeling studies were conducted by the Breast Cancer Working Group of the Cancer Intervention and Surveillance Modeling Network (CISNET) for use by the USPSTF (see the "Availability of Companion Documents" field).

Evidence Synthesis

Data Abstraction and Quality Rating

EPC staff abstracted details about the patient population, study design, analysis, follow-up, and results. By using predefined criteria developed by the USPSTF, two investigators rated the quality of each study as good, fair, or poor (described in Appendix B4 and B5 of the Evidence Synthesis [see the "Availability of Companion Documents" field]) and resolved discrepancies by consensus. EPC staff included only systematic reviews rated good quality in the report and randomized controlled trials rated fair or good quality in the meta-analysis.

Meta-Analysis of Mammography Trials

EPC staff updated the 2002 meta-analysis to include new findings from published trials of mammography screening compared with control participants for women ages 40 to 49 years that reported relative risk (RR) reduction in breast cancer mortality.Â Similar updates were conducted for other age groups for context.Â Breast cancer mortality results from trials were used to estimateÂ the pooled RR. EPC staffÂ calculated estimates from a random-effects model under the Bayesian data analytic framework by using the RBugs package in R, the same model as that used in the previous report. Appendix B6 of the Evidence Synthesis (see the "Availability of Companion Documents" field) provides additional details. EPC staffÂ used funnel plots to assess publication bias and L´Abbé plots to assess heterogeneity.

Analysis of Breast Cancer Surveillance Consortium (BCSC) Data

Background information and additional details about methods of the BCSC are described in Appendix B7 of the Evidence Synthesis (see the "Availability of Companion Documents" field). EPC staff obtained data from 600,830 women ages 40 years or older undergoing routine mammography screening from 2000 to 2005 at the BCSC sites from the BCSC Statistical Coordinating Center and stratified it by age in decades. Routine screening was having at least one mammography examination within the previous 2 years, which is consistent with current USPSTF recommendations. For women with several mammography examinations during the study, one result was randomly selected to be included in the calculations.

These data constitute selected BCSC data intended to represent the experience of a cohort of regularly screened women without preexisting breast cancer or abnormal physical findings.

Variables include the numbers of positive and negative mammography results and, of these, the numbers of true-negative and false-negative results based on follow-up data within one year of mammography screening. A positive mammography result was defined according to standardized terminology and assessments of the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) manual used by the BCSC. These include four categories: needs additional evaluation (category 0), probably benign with a recommendation for immediate follow-up (category 3), suspicious (category 4), or highly suggestive of malignancy (category 5). For women who had a positive screening mammography result, EPC staff evaluated data on the number of women undergoing additional imaging and biopsy, and diagnoses including invasive cancer, ductal carcinoma in situ (DCIS), and negative results. EPC staff considered additional imaging procedures and biopsies done within 60 days of the screening mammography to be related to screening. From these data, EPC staff calculated age-specific rates (numbers per 1000 women per round) of invasive breast cancer, DCIS, false-positive and false-negative mammography results, additional imaging, and biopsies. EPC staffÂ based true-positive and true-negative mammography results on invasive and noninvasive cancer diagnosis. Rates of additional imaging and rates of biopsies may be underestimated because of incomplete capture of these examinations by the BCSC.Â A sensitivity analysis of missing values was conducted, although this does not include records that were unavailable to the BCSC.

Model Analysis

Model Development

CISNET used 6 established models to estimate the outcomes across 20 mammography screening strategies that vary by age of initiation and cessation and by screening interval among a cohort of U.S. women. The 6 models were developed independently within the Cancer Intervention and Surveillance Modeling Network (CISNET) of the National Cancer Institute (NCI) and were exempt from institutional review board approval. They share common features and inputs but differ in some ways (Appendix Table 1 in the Model Analysis [see the "Availability of Companion Documents" field]). Model E (Erasmus Medical Center, Rotterdam, the Netherlands), model G (Georgetown University Medical Center, Washington, DC, and Albert Einstein College of Medicine, Bronx, New York), model M (M.D. Anderson Cancer Center, Houston, Texas), and model W (University of Wisconsin, Madison, Wisconsin, and Harvard Medical School, Boston, Massachusetts) include ductal carcinoma in situ (DCIS). Models E and W specifically assume that some portions of DCIS are nonprogressive and do not result in death. Model W also assumes that some cases of small invasive cancer are nonprogressive. Model S (Stanford University, Palo Alto, California) and model D (Dana-Farber Cancer Institute, Boston, Massachusetts) include only invasive cancer. Some groups model breast cancer in stages, but 3 (models E, S, and W) use tumor size and tumor growth. The models also differ by whether treatment affects the hazard for death from breast cancer (models G, S, and D), results in a cure for some fraction of cases (models E and W), or both (model M). Despite

these differences, in previous collaborations all the models came to similar qualitative estimates of the relative contributions of screening and treatment to observed decreases in deaths from breast cancer.

Model Overview

CISNET used 6 models to estimate the benefits, resource use (as measured by number of mammograms), and harms of 20 alternative screening strategies varying by starting and stopping age and by interval (annual and biennial) (Table 1 in the Model Analysis [see the "Availability of Companion Documents" field]). The models began with estimates of breast cancer incidence and mortality trends without screening and treatment and then overlayed screening use and improvements in survival associated with treatment. A cohort of women born in 1960 were followed for their entire lives, beginning at age 25 years. Breast cancer is generally depicted as having a preclinical, screening-detectable period (sojourn time) and a clinical detection point. On the basis of mammography sensitivity (or thresholds of detection), screening identifies disease in the preclinical screening-detection period and results in the identification of earlier-stage or smaller tumors than might be identified by clinical detection, resulting in reduction in breast cancer mortality. Age, estrogen receptor status, and tumor size- or stage-specific treatment have independent effects on mortality. Women can die of breast cancer or of other causes.

Model Data Variables

All 6 modeling groups used a common set of age-specific variables for breast cancer incidence, mammography test characteristics, treatment algorithms and effects, and nonbreast cancer competing causes of death (Appendix Table 2 in the Model Analysis [see the "Availability of Companion Documents" field]). In addition to these common variables, each model included model-specific inputs (or intermediate outputs) to represent preclinical detectable times, lead time, dwell time within stages of disease, and stage distribution in unscreened versus screened women on the basis of their specific model structure.

An age-period-cohort model was used to estimate what breast cancer incidence rates would have been without screening. This approach considers the effect of age, temporal trends in risk by cohort, and time period. Because data on future incidence of breast cancer was not available, the data were extrapolated forward assuming that future age-specific incidence increases as women age, as observed in 2000. To isolate the effect of technical effectiveness of screening and to assess the effect of screening on mortality while holding treatment constant, models assumed 100% adherence to screening and indicated treatment.

Three groups used the age-specific mammography sensitivity (and specificity) values observed in the Breast Cancer Surveillance Consortium (BCSC) program for detection of all cases of breast cancer (invasive and in situ). Separate values are used for initial and subsequent mammography performed at either annual or biennial intervals. Two of the models (D and G) used these data directly as input variables,Â and one model (S) used the data to calibrate the model. The other 3 models (E, M, and W) used the BCSC data as a guide and to fit sensitivity estimates from this and other sources.

All women who had estrogen receptor-positive invasive tumors received hormonal treatment (tamoxifen if women were younger than 50 at diagnosis and anastrozole if 50 or older) and nonhormonal treatment with an anthracycline-based regimen. Women with estrogen receptor-negative invasive tumors received nonhormonal therapy only. Women with DCIS who had estrogen receptor-positive tumors received hormonal therapy only. Treatment effectiveness was based on a synthesis of recent clinical trials and was modeled as a proportionate reduction in mortality risk or the proportion cured.

Benefits

The cumulative probability of unscreened women dying of breast cancer from age 40 years to death was estimated. Screening benefit was then calculated as the percentage of reduction in breast cancer mortality (vs. no screening). Life-years gained because of averted or delayed breast cancer death was also examined. Benefits were cumulated over the lifetime of the cohort to capture reductions in breast cancer mortality (or life-years gained) occurring years after the start of screening, after considering nonbreast cancer mortality.

Harms

As measures of the burden that a regular screening program imposes on a population, 3 different potential screening harms were examined: false-positive mammograms, unnecessary biopsies, and overdiagnosis. The rate of false-positive mammograms was defined as the number of mammograms read as abnormal or needing further follow-up in women without cancer divided by the total number of positive screening mammograms based on the specificity reported in the BCSC. Unnecessary biopsies were defined post hoc as the proportion of women with false-positive screening results who received a biopsy. Overdiagnosis was defined as the proportion of cases in each strategy that would not have clinically surfaced in a woman's lifetime (because of lack of progressive potential or death from another cause) among all cases arising from age 40 years onward.

Base-Case Analysis

Model results for the 20 strategies were compared to select the most efficient approach. In a decision analysis, a new intervention is considered more efficient than a comparison intervention if it results in gains in health outcomes, such as life-years gained or deaths averted, while consuming fewer resources (or costs). If the new intervention results in worse outcomes and requires a greater investment, it is inefficient and would not be considered for further use. In economic analysis, inefficient strategies are said to be "dominated" when this occurs. To rank the screening strategies, the results of each model were first examined independently. For a particular model, a strategy that required more mammographies (the measure of resource use) but had a lower relative percentage of mortality reduction (or life-years gained) was considered inefficient or dominated by other strategies. To evaluate strategies on the basis of results from all 6 models together, they were classified as follows: If a strategy was dominated in all or in 5 of 6 of the models, it was considered as dominated overall. If a strategy was not dominated in any of the models, it was classified as efficient. A strategy with mixed results across the models was classified as borderline.

After all dominated strategies were eliminated, the remaining strategies were represented as points on a graph plotting the average number of mammograms versus the percentage of mortality reduction (or life-years gained) for each model. The efficiency frontier for each graph was obtained by identifying the sequence of points that represent the largest incremental gain in percentage of mortality reduction (or life-years gained) per additional screening mammography. Screening strategies that fell on this frontier were the most efficient (that is, no alternative existed that provided more benefit for fewer mammographies performed).

Sensitivity Analysis

A sensitivity analysis was conducted to see whether conclusions about the ranking of strategies changed when the input variables varied. First, the effect of assuming that mammography sensitivity for a given age, screening round, and screening interval is 10 percentage points less than that observed was investigated. Second, the effect on the ranking of strategies when treatment included newer hormonal and nonhormonal adjuvant regimens (for example, taxanes) was examined. Third, because adjuvant therapy is unlikely to reach 100% of women as modeled in the base-case analysis, the ranking of strategies, if it is assumed that actual observed current treatment patterns apply to the cohort, was reassessed.

Model Validation and Uncertainty

Each model has a different structure and assumptions and some varying input variables, so no single method can be used to validate results against an external gold standard. For instance, because some models used results from screening trials (or SEER [Surveillance, Epidemiology and End Results] data) for calibration or as input variables, comparisons of projected mortality reductions to trial results cannot be used to validate all of the models. In addition, the results of this analysis, which used 100% actual screening for all women at specified intervals, cannot be directly compared with screening trial results in which invitation to screening and participation varied. Overall, using 6 models to project a range of plausible screening outcomes provided implicit cross-validation, with the range of results from the models as a measure of uncertainty.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important,

but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

**A*, *B*, *C*, *D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the Task Force in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study

quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875 [5 references].

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:

Level of Certainty	Description
	• The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

COST ANALYSIS

A total of 298 abstracts relevant to costs of breast cancer screening were identified by searches, and 29 full text articles were retrieved for further review. Studies focused on costs and cost savings of screening, comparisons of screening strategies or programs, and costs for older women.

Data from 10,048 women screened at an integrated cancer center in the United States were used to estimate the financial impact of a screening mammography program, including costs for mammography, diagnostic procedures, and therapeutic procedures. Overall results showed that screening mammography operated at a loss, and payer reimbursement was not sufficient to cover overhead costs. The screening mammography program was not financially viable without clear criteria to increase the yield of diagnostic and therapeutic procedures.

For additional information refer toÂ Appendix C1 in theÂ EvidenceÂ Synthesis (see the "Availability of Companion Documents" field).

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review: Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the whole U.S. Preventive Services Task Force before final recommendations are confirmed.

Recommendations of Others: Recommendations for screeningÂ from the following groups were discussed: the American Medical Association,Â the American Cancer Society, the American College of Physicians, the American College of Obstetricians and Gynecologists,Â the Canadian Task Force on Preventive Health Care, the American Academy of Family Physicians, the National Comprehensive Cancer Network, and the World Health Organization.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the U.S. Preventive Services Task Force (USPSTF): On December 4, 2009, the USPSTF unanimously voted to update the language of their recommendation regarding women under 50 years of age to clarify their original and continued intent. The following recommendations reflect that change.

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendations and Evidence

- The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. **This is a B recommendation.**
- The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient´s values regarding specific benefits and harms. **This is a C recommendation.**
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older. **This is an I statement.**

- The USPSTF recommends against teaching breast self-examination (BSE). **This is a D recommendation.**
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older. **This is an I statement.**
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer. **This is an I statement.**

Clinical Considerations

Patient Population Under Consideration

This recommendation statement applies to women 40 years or older who are not at increased risk for breast cancer by virtue of a known underlying genetic mutation or a history of chest radiation.

Assessment of Risk

Increasing age is the most important risk factor for breast cancer for most women. Women without known deleterious genetic mutations (such as BRCA1 or BRCA2) may still have other demographic, physical, or historical risk factors for breast cancer, but none convey a clinically important absolute increased risk for cancer.

Screening Tests

In recent decades, the early detection of breast cancer has been accomplished by physical examination by a clinician (CBE), by a woman herself (BSE), or by mammography. Standardization of mammography practices enacted by the Mammography Quality Standards Act have led to improved mammography quality. Clinicians should refer patients to Mammography Quality Standards Act–certified facilities, a listing of which is available at www.fda.gov/cdrh/mammography/certified.html.

Screening Intervals

In trials that demonstrated the effectiveness of mammography in decreasing breast cancer mortality, screening was performed every 12 to 33 months. The evidence reviewed by the USPSTF indicates that a large proportion of the benefit of screening mammography is maintained by biennial screening, and changing from annual to biennial screening is likely to reduce the harms of mammography screening by nearly half. At the same time, benefit may be reduced when extending the interval beyond 24 months; therefore the USPSTF recommends biennial screening.

Treatment

Effective treatments, including radiation, chemotherapy (including hormonal treatment), and surgery, are available for invasive carcinoma. Although the standard treatments women receive for ductal carcinoma in situ (DCIS) include surgical approaches as well as radiation and hormonal therapy, considerable debate exists about the optimal treatment strategy for this condition.

Considerations for Practice Regarding I Statements

Clinical Breast Examination

Potential Preventable Burden. The evidence for CBE, although indirect, suggests that CBE may detect a substantial proportion of cases of cancer if it is the only screening test available. In parts of the world where mammography is infeasible or unavailable (such as India), CBE is being investigated in this way.

Potential Harms. The potential harms of CBE are thought to be small but include false-positive test results, which lead to anxiety and breast cancer worry, as well as repeated visits and unwarranted imaging and biopsies.

Costs. The principal cost of CBE is the opportunity cost incurred by clinicians in the patient encounter.

Current Practice. Surveys suggestÂ that the CBE technique used in the United States currently lacks a standard approach and reporting standards. Clinicians who are committed to spending the time on CBE would benefit their patients by considering the evidence in favor of a structured, standardized examination.

Digital Mammography

Potential Preventable Burden. Digital mammography detects some cases of cancer not identified by film mammography; film mammography detects some cases of cancer not identified by digital mammography. Overall detection is similar for many women. For women who are younger than 50 years or have dense breast tissue, overall detection is somewhat higher with digital mammography. It is not clear whether this additional detection would lead to reduced mortality from breast cancer.

Potential Harms. The possibility of false-positive test results is similar for film and digital mammography. It is uncertain whether overdiagnosis occurs more with digital mammography than with film mammography.

Costs. Digital mammography is more expensive than film mammography.

Current Practice. Some clinical practices are now switching their mammography equipment from film to digital. This may curtail the availability of film mammography in some areas.

Magnetic Resonance Imaging

Potential Preventable Burden. Studies of the use of contrast-enhanced MRI for breast cancer screening have been conducted only in very high-risk populations.

In these studies, MRI detected more cases of cancer than did mammography. It is unknown whether detecting these additional cases of cancer would lead to reduced breast cancer mortality.

Potential Harms. Contrast-enhanced MRI requires the injection of contrast material. Studies of MRI screening have shown that MRI yields many more false-positive results than does mammography. Magnetic resonance imaging has the potential to be associated with a greater degree of overdiagnosis than mammography.

Costs. Magnetic resonance imaging is much more expensive than either film or digital mammography.

Current Practice. Magnetic resonance imaging is not currently used for screening women at average risk for breast cancer.

Screening Mammography in Women 75 Years or Older

Potential Preventable Burden. No women 75 years or older have been included in the multiple randomized clinical trials of breast cancer screening. Breast cancer is a leading cause of death in older women, which might suggest that the benefits of screening could be important at this age. However, 3 facts suggest that benefits from screening would probably be smaller for this age group than for women aged 60 to 69 years and probably decrease with increasing age: 1) the benefits of screening only occur several years after the actual screening test, whereas the percentage of women who survive long enough to benefit decreases with age; 2) a higher percentage of the type of breast cancer detected in this age group is the more easily treated estrogen receptor–positive type; and 3) women of this age are at much greater risk for dying of other conditions that would not be affected by breast cancer screening.

Potential Harms. Screening detects not only cancer that could lead to a woman´s death but also cancer that will not shorten a woman's life. Women cannot benefit from—but can be harmed by—the discovery and treatment of this second type of cancer, which includes both cancer that might someday become clinically apparent and cancer that never will. Detection of cancer that would never have become clinically apparent is called overdiagnosis, and it is usually followed by overtreatment. Because of a shortened life span among women 75 years or older, the probability of overdiagnosis and unnecessary earlier treatment increases dramatically after about age 70 or 75 years. Overdiagnosis and unnecessary earlier treatment are important potential harms from screening women in this age group.

Current Practice. Studies show that many women 75 years or older are currently being screened.

Useful Resources

Other USPSTF recommendations on screening for genetic susceptibility for breast cancer and chemoprevention of breast cancer are available on the Agency for Healthcare Research and Quality Web site (www.preventiveservices.ahrq.gov).

Definitions:

What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly

Level of Certainty	Description
	affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

CLINICAL ALGORITHM(S)

None available

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Benefits of Detection and Early Intervention

- There is convincing evidence that screening with film mammography reduces breast cancer mortality, with a greater absolute reduction for women aged 50 to 74 years than for women aged 40 to 49 years. The strongest evidence for the greatest benefit is among women aged 60 to 69 years.

- Among women 75 years or older, evidence of benefits of mammography is lacking.
- Adequate evidence suggests that teaching breast self-examination (BSE) does not reduce breast cancer mortality.
- The evidence for additional effects of clinical breast examination (CBE) beyond mammography on breast cancer mortality is inadequate.
- The evidence for benefits of digital mammography and magnetic resonance imaging (MRI) of the breast, as a substitute for film mammography, is also lacking.

POTENTIAL HARMS

Harms of Detection and Early Intervention

- The harms resulting from screening for breast cancer include psychological harms, unnecessary imaging tests and biopsies in women without cancer, and inconvenience due to false-positive screening results. Furthermore, one must also consider the harms associated with treatment of cancer that would not become clinically apparent during a woman's lifetime (overdiagnosis), as well as the harms of unnecessary earlier treatment of breast cancer that would have become clinically apparent but would not have shortened a woman´s life. Radiation exposure (from radiologic tests), although a minor concern, is also a consideration.
- Adequate evidence suggests that the overall harms associated with mammography are moderate for every age group considered, although the main components of the harms shift over time. Although false-positive test results, overdiagnosis, and unnecessary earlier treatment are problems for all age groups, false positive results are more common for women aged 40 to 49 years, whereas overdiagnosis is a greater concern for women in the older age groups.
- There is adequate evidence that teaching breast self-examination (BSE) is associated with harms that are at least small. There is inadequate evidence concerning harms of clinical breast examination (CBE).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.
- Recommendations are based on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.
- The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policy-makers should understand the evidence but individualize decision making to the specific patient or situation.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Personal Digital Assistant (PDA) Downloads

Pocket Guide/Reference Cards
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for breast cancer. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2009 Dec.

U.S. Preventive Services Task Force. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2009 Nov 17;151(10):716-26, W-236. PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2009; addendum released 2009 Dec)

GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

GUIDELINE DEVELOPER COMMENT

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task Force has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. Task Force members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Screening for breast cancer: recommendations and rationale. Ann Intern Med 2002 Sep 3;137(5 Part 1):344-6. [10 references]

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Also available fromÂ Annals of Internal Medicine Online.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go toÂ http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295. (Outside the United States: 1-410-381-3150;Toll-free TDD service; hearing impaired only: 888-586-6340.)

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Evidence Reviews:

- Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, Nygren P, Humphrey L. Screening for breast cancer: systematic evidence review update for the U.S. Preventive Services Task Force. Evidence Synthesis No. 74. AHRQ Publication No. 10-05142-EF-1. Rockville, Maryland: Agency for Healthcare Research and Quality. November 2009.Â Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.
- Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, Humphrey L. Screening for breast cancer: an updateÂ for the U.S. Preventive Services Task Force. Ann Intern Med. 2009;151:727-737. Electronic copies: Available from the Annals of Internal Medicine Web site.
- Mandelblatt JS, Cronin KA, Bailey S, Berry DA, de Koning HJ, Draisma G, Huang H, Lee SJ, Munsell M, Plevritis SK, Ravdin P, Schechter CB, Sigal B, Stoto MA, Stout NK, van Ravesteyn NT, Venier J, Zelen M, Feuer EJ; for the Breast Cancer Working Group of the Cancer Intervention and Surveillance Modeling Network (CISNET). Effects of mammography screening under different screening schedules: model estimates of potential benefits and harms. Ann Intern Med. 2009 Nov 17;151(10):738-747. Electronic copies: Available from the Annals of Internal Medicine Web site.

The following are also available:

- Screening for breast cancer using film mammography: clinical summary of U.S. Preventive Services Task Force recommendation. Rockville (MD): Agency for Healthcare Research and Quality, 2009. 2 p. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.
- A continuing medical education (CME) course is available from the Annals of Internal Medicine Web site.

Background Articles:

- Barton M et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med. 2007;147:123-127.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med. 2007;147:117-122. [2 references]

- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875. [5 references].

Electronic copies: Available from U.S. Preventive Services Task Force (USPSTF) Web site.

The following is also available:

- The guide to clinical preventive services, 2009. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2009. 228 p. Electronic copies available from the AHRQ Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

The Electronic Preventive Services Selector (ePSS), available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

PATIENT RESOURCES

The following are available:

- Screening for breast cancer: U.S. Preventive Services Task Force recommendations. Summaries for patients. 2009 Nov 17. Available from the Annals of Internal Medicine Web site.
- Women: Stay Healthy at Any Age – Checklist for Your Next Checkup. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 07-IP005-A. February 2007. Electronic copies: Available in English and Spanish from the USPSTF Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a new tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov.

them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on June 30, 1998. The information was verified by the guideline developer on December 1, 1998. The summary was updated on March 6, 2002. The updated information was verified by the guideline developer as of March 8, 2002. This summary was updated again on September 4, 2002. This summary was updated by ECRI Institute on November 23, 2009. The information was verified by the guideline developer on December 30, 2009. This summary was updated to reflect the information in the addendum on January 8, 2010.

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